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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/013,049	12/10/2001	Richard James Riehle	10086/2	2668

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/013,049

Applicant(s)

RIEHLE ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-29 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-21 and 35-38 is/are rejected.
- 7) ☒ Claim(s) 22-29, 31-34 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/06 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-21 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The additional step of contacting the composition with "at least one microorganism, or at least on enzyme located from the at least one microorganism, in an amount, and at a pH and temperature effective to dehalogenate residual quantities of organically bound halogen" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claims 1-21 and 35-38 encompass a treatment process that includes treating a composition containing a wet strength polyamine-epihalohydrin resin comprising a solids

Art Unit: 1744

content of at least 15 wt% with an enzymatic agent to inhibit, reduce or remove a CPD-forming species. The final amount of CPD-forming species remaining in the composition after the enzyme treatment is defined in terms of the "ACID TEST". That is, the treated composition when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD.

Review of the originally filed disclosure includes 38 Examples.

Example 1 is drawn solely to the manufacture of a wet strength polyamine-epihalohydrin composition with a solids content of 21.08% and includes CPD-forming species.

Example 2 is drawn to an enzymatic treatment of the composition of Example 1. The results of Example 2 do not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD". See table 1.

Example 3 is drawn to a biodehalogenation treatment of the treated composition of Example 2. It is noted that the treated composition of Example 2 is diluted prior to treatment with the microorganisms. As shown in Table 1 the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD".

Example 4 is drawn to a diluted composition of Example 1. The starting composition has a solids content less than 15 wt%.

Example 5 is drawn to a comparison of a paper product using the treated compositions of Examples 3 and 4.

Examples 6-19 are drawn to enzyme treatments of high solids (at least 15 wt%) wet strength polyamine-epihalohydrin compositions. While a high solids composition was treated with the enzyme composition, the tabulated data does not establish that the treated composition

Art Unit: 1744

“when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”. See table 3.

Example 20 is drawn to a combined enzyme-biodehalogenation treatment method of a diluted (less than 15 wt%) starting composition. While the “ACID TEST” establishes that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”, see table 4, the starting composition did not include a solids composition of at least 15 wt %.

Example 21 is similar to Example 20 but employs twice as much enzyme.

Example 22 is similar to Examples 20 and 21. This example employs a different starting composition but the solids content is still less than 15 wt%.

Example 23 is drawn to biodehalogenation of a starting composition of at least 15 wt%.

Example 24 is drawn to a sequential enzyme-biodehalogenation treatment process with a starting composition of at least 15 wt%. While the “ACID TEST” establishes that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”, see table 11, the treatment process employed both an enzyme treatment and biodehalogenation treatment.

Example 25 is drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. While the “ACID TEST” establishes that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”, see table 12, the treatment process employed both an enzyme treatment and biodehalogenation treatment.

Art Unit: 1744

Examples 26-30 are limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Examples 31 and 32 are drawn to an enzyme treatment of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”. See tables 21 and 22.

Examples 33 and 34 are limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Example 35 is drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”. See tables 25 and 26.

Example 36 is limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Examples 37 and 38 are drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”. See tables 28 and 29.

In summary, only Examples 3, 24 and 25 are drawn to treatment methods that treat a starting composition with a solids content of at least 15 wt% wherein the treatment method includes the claimed enzyme treatment and establishes that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”.

Art Unit: 1744

However, it is apparent to one of ordinary skill in the art that the biodehalogenation **step is critical to the invention** since each of these examples also included a biodehalogenation step as part of the treatment process that resulted in a treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”. Note the examples that were drawn solely to an enzyme treatment of a starting composition of at least 15 wt% did not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 250 ppm dry basis of CPD”.

Allowable Subject Matter

4. Claims 22-29, 31-34 and 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. With respect to the rejection of Claims 1-21 and 35-38 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling, Applicants argue (See pages 8-13 of the response filed 4/14/06) that the rejection is improper because the instant specification, including the examples, can not be considered as evidence of “unpredictability”.

First, Applicants admit that, while Examples 3, 24, and 25 do utilize a biodehalogenation step, other methods are known and disclosed in the instant specification for removing CPD present in the samples.

Art Unit: 1744

In response, while this may be true, Examples 3, 24 and 25 and Applicants' comments clearly evidence that removing CPD present in the samples is critical to the **claimed** invention. Note Applicants' comments are not commensurate in scope with the instant claim language. Applicants' comments indicate that the claims should not be limited to biodehalogenation because other CPD removing steps are known in the art. These comments indicate that the instant claims should at least include a step of removing CPD from the sample, while not necessarily being limited to a biodehalogenation step.

Applicants also challenge the Examiner with respect to the references within the specification concerning the "unpredictability" in the art. Applicants stress that the reference on page 9 concerns the unpredictability of removing "CPD-forming species" rather than "available CPD species".

In response, the method of the instant claims does involve removing "CPD-forming species" and as a result is considered to be an unpredictable process in the art as evidenced by the specification at page 9 regardless if the methods of removing available CPD species is predictable.

Finally, Applicants comment that many of the examples provided in the specification are not commensurate in scope with the instant claims and as a result cannot be used as evidence of unpredictability in the art.

In response, the Examiner was not relying on the examples to show unpredictability in the art, rather the Examiner points to the examples as evidence that the biodehalogenation step is a critical feature of the invention since the other examples of the 114 page specification, which includes 38 examples, do not support the instant claim language because the resulting product of

Art Unit: 1744

the performed methods does not meet the claim limitation of “releases less than about 100 ppm dry basis of CPD”.

In conclusion, the Examiner is of the position that when presented with the facts above, one of ordinary skill in the art would recognize that the biodehalogenation step is critical to obtaining the storage stable product required of the instant claim language.

6. With respect to the rejection of Claims 1-29 and 31-35 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, this rejection has been withdrawn in view of Applicants' amendments to the claims and associated comments (See pages 13-14 of the response filed 4/14/06).

7. With respect to the rejection of Claims 1-12, 14-16, 18-25 and 35-37 under 35 U.S.C. 103(a) as being unpatentable over Richle et al.(US 6,554,961 or US 2003/0205345) in view of Bull et al.(US 5,470,742), this rejection has been withdrawn in view of Applicants' amendments to the claims and associated comments (See pages 14-17 of the response filed 4/14/06).

8. With respect to the rejection of Claims 1-13, 19-21 and 35-38 under 35 U.S.C. 103(a) as being obvious over Bull et al.(US 5,470,742) in view of Miller et al.(US 5,171,795), this rejection has been withdrawn in view of Applicants' amendments to the claims and associated comments (See pages 17-20 of the response filed 4/14/06).

Art Unit: 1744

9. With respect to the rejection of Claims 1-13 and 19-21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-13 and 15-20 of U.S. Patent No. 6,554,961 in view of Bull et al.(US 5,470,742), this rejection has been withdrawn in view of Applicants' amendments to the claims and associated comments (See pages 21-22 of the response filed 4/14/06).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner

Application/Control Number: 10/013,049

Page 10

Art Unit: 1744

Primary Examiner
Art Unit 1744

WHB